EXHIBIT B1-B

rejected the Administration's effort to set reimbursement for covered drugs at the provider's actual cost and instead reset the Medicare reimbursement rate for covered drugs at 95% of AWP. *See* Pub. L. No. 105-33 § 4566(a) (1997) (codified at 42 U.S.C. § 1395u(o)). The legislative and regulatory record generated during this period leaves no doubt that it was well-known that published AWPs substantially exceeded providers' actual acquisition costs.

In 1997, the Administration proposed reducing Medicare drug reimbursement to the amount the provider actually paid for the drug.[24] In support of the President's proposal, Secretary of HHS Donna Shalala outlined the factual and policy grounds on which the Administration opposed using AWP to determine Medicare reimbursement:

> Medicare pays the [AWP] for covered drugs. ***However, the AWP is not the average price actually charged by wholesalers to their customers. Rather, it is a "sticker" price set by drug manufacturers and published in several commercial catalogs.*** . . . We believe that physicians should be paid for their professional services and not derive a profit from drugs furnished incident to their professional services. Also, ***the current payment rules allow an increase in the AWP even if the cost to the physician remains constant.*** This creates an incentive for physicians to furnish the most profitable drugs. Our proposal would remove this incentive so that the decision to furnish a particular drug is more directly based on medical considerations.

1997 Senate Hearings at 265 (emphasis added) (Defs. App. Ex. R).

Despite these policy arguments, Congress rejected the Administration's proposal to abandon AWP-based reimbursements and to reduce Medicare reimbursements to actual acquisition costs. Instead, in the BBA, Congress amended the Medicare Act to set the Medicare

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24 *See Medicare Provisions in the President's Budget: Hearing Before the Subcomm. on Health of the House Comm. on Ways and Means*, 105th Cong. at 11 (1997 (testimony of HCFA Administrator Bruce Vladek) (Defs. App: Ex. Q); *President's Fiscal Year 1998 Budget Proposal for Medicare, Medicaid and Welfare: Hearings Before the Senate Comm. on Finance*, 105th Cong. at 265 (1997) ("1997 Senate Hearings") (testimony of Secretary of HHS Donna Shalala) (Defs. App. Ex. R).

allowable reimbursement at 95% of AWP and to eliminate estimated acquisition cost altogether as a criterion for Medicare reimbursements. *See* Pub. L. No. 105-33 § 4566(a) (1997) (codified at 42 U.S.C. § 1395u(o)).

Although Congress did not include a definition of AWP in the statute, Congress recognized that AWP substantially exceeded acquisition cost. For example, the House report noted:

> The Inspector General for the Department of Heath and Human Services has found evidence over the past several years that Medicare has paid significantly more for drugs and biologicals than physicians and pharmacists pay to acquire such pharmaceuticals. ***For example, the Office of Inspector General reports that Medicare reimbursement for the top 10 oncology drugs ranges from 20 percent to nearly 1000 percent per dosage more than acquisition costs.***

Balanced Budget Act of 1997: Report of the House Comm. on the Budget, H. Rep. No. 105-149 at 1354 (1997) (emphasis added) (Defs. App. Ex. S).

In its regulations implementing the BBA, HCFA again noted that AWP does not represent actual acquisition costs. *See* 42 C.F.R. § 405.517 (2001); *New Payment Limit for Drugs and Biologicals*, HCFA Pub. 60AB, Transmittal No. AB-97-25 (Jan. 1998) (Defs. App. Ex. T) (noting that "this change in payment allowance [from 100% of AWP to 95% of AWP] recognizes the fact that AWP is not a true discounted price and, therefore, does not reflect the cost to the physician or supplier"); 63 Fed. Reg. 58,814-01, 58,849 (Nov. 2, 1998) ("From a series of OIG reports spanning the past 10 years, it is clear that the AWP is higher than the amount typically paid for drugs by physicians who bill the program.").

4. Continued Debate About Use of AWP From 1997 to 2003

Shortly after passage of the BBA, President Clinton criticized the AWP-based Medicare reimbursement policy in a national radio address. Even as he characterized the statutory reimbursement system as wasteful and abusive, President Clinton also stated there was nothing illegal about it:

> ***Sometimes the waste and abuse aren't even illegal; they're just embedded in the practices of the system.*** Last week, the Department of Health and Human Services confirmed that our Medicare program has been systematically overpaying doctors and clinics for prescription drugs -- overpayments that cost taxpayers hundreds of millions of dollars . . . . Now, ***these overpayments occur because Medicare reimburses doctors according to the published average wholesale price -- the so-called sticker price -- for the drugs. Few doctors, however, actually pay the full sticker price.*** In fact, some pay just one tenth of the published price.

White House Office of the Press Secretary, *Remarks by the President in Radio Address to the Nation*, 1997 WL 767416, at *1-2 (White House Dec. 13, 1997) (Defs. App. Ex. U).

To remedy these legal overpayments, the President announced, "I'm sending to Congress again the same legislation I sent last year -- legislation that will ensure that doctors are reimbursed no more, and no less, than the price they themselves pay for the medicines they give Medicare patients." *Id.* at *2. However, Congress did not enact the legislation proposed by President Clinton.

After legislative efforts to repeal the BBA's Medicare drug reimbursement provisions failed, HCFA tried administratively to accomplish the same objective. In May 2000, Secretary Shalala informed Congress that HCFA was preparing to instruct Medicare carriers to cease using AWPs published in industry publications and to commence using lower price data that was

recently estimated through an alternative government survey for certain drugs.[25] In July 2000, 89 members of Congress wrote Secretary Shalala objecting to her plan. *See* Letter to HHS Secretary Donna E. Shalala from 89 Members of Congress (July 28, 2000) (Defs. App. Ex. V) (emphasis added). These 89 Members stressed that oncologists rely on Medicare paying a markup on drugs to offset the fact that Medicare underpays them for their professional services:

> . . . [O]ncologists are chronically underpaid for their drug administration services in treating cancer patients, a fact that is widely recognized, including in your letter announcing the plan to reduce reimbursement. ***If reimbursement for drugs is drastically reduced, many physicians will be unable to continue providing cancer care in their offices, and patients will be deprived of a humane, convenient and cost-effective treatment option.***

Id. (emphasis added).

In September 2000, then-Senator Ashcroft introduced a bill called the "Cancer Care Preservation Act" to bar HCFA from implementing "any reduction to the rates of reimbursement for outpatient cancer therapy services under the Medicare program." 146 Cong. Rec. S8019-05, S8023 (Sept. 5, 2000). He argued that Medicare drug reimbursement should exceed the price paid by physicians and hospitals because "these margins . . . help cover costs for professional services, which are inadequately reimbursed" *Id.* Senator Ashcroft feared that HCFA's plan to cut drug reimbursement by "changing the definition" of AWP would "force doctors to send seniors with cancer out of the community settings" and into more expensive hospital settings, which would cause overall Medicare spending to rise. 146 Cong. Rec. at S8022.

HCFA abandoned its reimbursement reform plan, and in December 2000, Congress passed the Medicare, Medicaid and SCHIP Benefits Improvement and Protection Act of 2000

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[25] *See* Letter to Representative Thomas Bliley from Secretary of HHS Donna E. Shalala (May 31, 2000) (Def. App. Ex. O).

("BIPA"), Pub. L. No. 106-554, 114 Stat. 2763 (2000). BIPA, *inter alia*, prohibited any change in Medicare Part B reimbursement pending further study, and directed the General Accounting Office ("GAO") to study reimbursement for drugs under Part B and to determine the average prices at which providers acquired those drugs. *See id.* at § 429(a). Congress further directed the GAO to consider whether changes to Medicare payment for professional services would be warranted if the drug reimbursement methodology were changed. *See id.* at § 429(a)(3).

The GAO issued its report in September 2001. *See Medicare: Payments for Covered Outpatient Drugs Exceed Providers' Cost, GAO Report to Congressional Committees* (Sept. 2001) (Defs. App. Ex. W). GAO reported that AWP is "often described as a 'list price,' 'sticker price,' or 'suggested retail price,'" and "is not necessarily the price paid by a purchaser." *Id.* at 9. The GAO also concluded that "Medicare's AWP-based methodology does not incorporate information on actual transaction prices." *Id.* at 25. In response to the position of oncologists that "profits on the drugs compensate for what they regard as underpayments for their administration," GAO noted that "[it] should be a principle of Medicare payment policy to pay for each service appropriately and not to rely on potential payments for some services to offset inadequate payments for complimentary services." *Id.* In subsequent congressional hearings, CMS Administrator Thomas Scully testified that "[t]he current system, which results in Medicare and beneficiaries paying excessive prices for certain prescription drugs, must be fixed. At the same time, we need to be certain that Medicare pays providers appropriately for their services when they furnish drugs to beneficiaries."[26]

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[26] *See Testimony of Thomas A. Scully, Administrator Centers for Medicare & Medicaid Services, on Reimbursement & Access To Prescription Drugs Under Medicare Part B, Senate Finance Comm. Subcomm. on Health*, at 2 (March 14, 2002) (Defs. App. Ex. X); *see also Testimony of the Honorable Thomas A. Scully, Hearing*

In August 2003, CMS sought public comment on four options for a comprehensive revision of its methodology for reimbursement of drugs under Medicare Part B to eliminate the overpayments documented by previous studies. 68 Fed. Reg. 50428, 50431-36 (Aug. 20, 2003). CMS also heeded the recommendations of the GAO, HHS IG, and the American Society of Clinical Oncology that "revisions to the payment methodology for drugs should coincide with the increase in practice expenses for drug administration services." *Id.* at 50437. Accordingly, CMS also proposed rule changes that would increase physician services reimbursements at the same time drug reimbursements were lowered. *See id.* at 50436-40.

5. Resolution of the Debate in November 2003

The proposed administrative revisions to the reimbursement system have been superceded by very recent congressional action. In the landmark 2003 Medicare Act, passed on November 25, 2003, Congress took action to revise both the AWP-based reimbursement system for Part B drugs and reimbursement for physician services in administering those drugs. The House-Senate Conference Report on this legislation explains that AWP "has been based on prices reported by drug manufacturers, that are published in industry reference publications or drug price compendia." Joint Explanatory Statement at 146. "There are no uniform criteria for reporting those numbers [and] these reported numbers do not reflect discounts that manufacturers and wholesalers customarily offer to providers and physicians." *Id.* Moreover, "AWP has never been defined in either statute or regulation." *Id.* Referring to the HHS IG and GAO reports summarized above, the Conference Report finds that "[t]here is substantial evidence that AWPs

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on Medicare Payments for Currently Covered Prescription Drugs, House Ways and Means Comm. Subcomm. on Health, at 1 (Oct. 3, 2002) (Defs. App. Ex. Y) (same).

for many Medicare-issued products far exceed the acquisition cost paid by suppliers and physicians." *Id.*

The Conference Report also recognized that "[s]ome physicians assert that the overpayment for drugs covers underpayment for practice expenses" and that "Medicare does not adequately reimburse them for the practice expenses associated with providing care in outpatient settings." *Id.* The Conference Report explains that Congress at last intends to address this long-standing conundrum: "This section reduces the overpayment for drugs and biologicals, while increasing physician practice expenses." *Id.* Indeed, the statute provides that the Secretary shall not implement the revisions to the payment methodology for drugs unless he "concurrently" makes the adjustments to physician reimbursement authorized by the statute. 2003 Medicare Act § 303(f).

The new legislation maintains reimbursement at 95% of AWP for the balance of this calendar year. *Id.* § 303(b). In 2004, payments will generally equal 85% of AWP. *Id.*[27] Beginning in 2005, drugs will be reimbursed under either an average sales price methodology or through a competitive acquisition program, *id.*, both of which are spelled out in the legislation. *Id.* § 303(c) and (d). *See* Joint Explanatory Statement at 192. The bill also requires the Secretary, beginning in 2004, to recognize the value of physician services in administering outpatient drugs in setting physician reimbursement rates. 2003 Medicare Act § 303(a), *see* Joint Explanatory Statement at 144-45.

Congress has thus acted to settle the controversy over reimbursement of Medicare Part B drugs that has raged since before the Part B program began. Throughout the many years of

[27] The Secretary is authorized to substitute a different percentage, but not lower than 80%. Certain drugs will continue to be reimbursed at 95% of AWP. *Id.*

ongoing debate and reimbursement reform efforts, three points have been abundantly clear: (1) AWP is an undiscounted list price or "sticker price" that is substantially higher than the price pharmacists or doctors pay for prescription drugs, (2) HHS and then Congress permitted Part B drugs to be reimbursed on the basis of AWP because of concerns over the adequacy of reimbursement for physician services; and (3) the AWP-based reimbursement system for Part B drugs could not be abandoned until action was taken to address reimbursement for the costs of administering those drugs.

II. ARGUMENT

In light of the regulatory and legislative history described above, all of which may be considered by the Court in the context of these motions to dismiss,[28] the State's core claims that Medicare, New York Medicaid and EPIC officials were deceived about the nature of AWPs cannot stand. This is demonstrated in Part A below. In Part B, we explain why all of the State's claims should be dismissed for lack of specificity.

In Parts C-G below, we show that each one of the State's causes of action does not or cannot pertain to certain portions of the State's claims (e.g. to certain co-payors' claims, or to claims for drugs sold to doctors, or to claims for drugs sold to retail pharmacies) and that the remaining portions of each claim suffer from additional substantive deficiencies that require dismissal.

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[28] *See* cases cited in footnote 4 above.

A. Given the Public Record Concerning AWPs, All of the State's Claims Fail Because The Government Could Not Have Been Deceived by Reported AWPs

At the core of all of the State's claims is the assertion that the State and the federal government were deceived when they chose to use AWP as a reimbursement benchmark for Medicaid, Medicare and EPIC.[29] The public record described above, however, defeats this core contention as a matter of law.

AWP is not defined anywhere in law or regulation, other than by reference to the AWPs published by third-party price reporting services. For decades the government and the industry have understood that the AWPs reported by the price reporting services were "undiscounted list prices" or "sticker prices" that often bore no relationship to prices at which providers could purchase drugs. The State cannot prevail on any claim that the various price reporting activities of the defendants were deceptive or misleading to Medicaid, Medicare or EPIC officials. In fact, the operating assumption of those agencies for years has been that the published AWPs -- as with any "sticker price" or "undiscounted list price -- *are* above the actual market cost of acquiring the product. The State's bald contention that the government was deceived by published AWPs is belied by decades of government reports, regulatory and legislative history and public accounts to the contrary.

In fact, as set forth in detail above, the drug reimbursement debate that has raged in Congress and the agencies for years has not been about whether AWPs reflect "real" market prices or whether they were "inflated;" it has been about whether to continue to use AWPs as a reimbursement benchmark in order to make up (through drug reimbursements) for perceived

[29] As discussed below, proof of deception or false statements is an element of the claims alleged in Counts One (Deceptive Acts and Practices), Two (Repeated and Persistent Fraud) and Five (Obtaining Public Funds by False Statements). In addition, the lack of deception defeats the state's Commercial Bribery and Medicaid Kickbacks and Fraud claims (Counts Three and Four), which require proof of corrupt or fraudulent intent.

under-reimbursements to oncologists and others (e.g. New York pharmacists) for their professional services. The debate at the federal level was only recently resolved in late November 2003 when Congress passed legislation to phase out AWP-based reimbursement in conjunction with increased reimbursement for physician services. All of this illustrates the key point: neither the federal nor the state government has been "deceived" by AWPs; instead, each has assumed that AWPs were often significantly higher than actual acquisition costs and debated whether to use them as reimbursement benchmarks.

In addition, two facts about the New York Medicaid and EPIC programs, in particular, further defeat any contention that New York officials were deceived into thinking that AWPs reflected actual market prices for certain pharmaceuticals. First, for at least a decade the New York Medicaid program has chosen not even to use AWPs as a reimbursement benchmark for physician-administered drugs, which include the Medicare Part-B covered drugs that are the only products identified in the complaints. Those drugs are reimbursed under the New York Medicaid program at the physicians' actual cost.[30] The New York Medicaid program chose this non-AWP based reimbursement approach, which results in lower reimbursements to physicians, in light of studies like the 1992 OIG study discussed above which showed that AWPs were up to 83% higher than actual costs for certain New York physician-administered chemotherapy drugs. *See* Def. App. Ex. G. Far from being "deceived" by AWPs, New York made a policy decision to reimburse for these drugs at actual acquisition costs, while continuing to reimburse for drugs sold in the pharmacy market on the basis of AWPs for different policy reasons.

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30 N.Y. Soc. Serv. Law § 367-a(9)(a). As noted above, EPIC does not even cover physician-administered drugs.

Second, as discussed above, New York has statutory authority to obtain pricing data directly from pharmaceutical manufacturers. In fact, through its EPIC Program, for years New York has actually received, directly from pharmaceutical companies, detailed quarterly statements of the "Average Manufacturers' Price" ("AMP") for drugs covered by EPIC, as well as the "Best Price" for certain drugs. *See* Def. App. Ex. M at 5-7. This pricing data has provided the State with a simple way to determine whether reported AWPs (and other pricing information such as wholesale acquisition costs, or "WACs") are higher than the "average manufacturers price," and by how much. Plainly, the State cannot have been deceived by AWPs when it has had the means to compare them to another published price point with a statutorily defined meaning.

At bottom, the State's assertions that it and the federal Medicare program were deceived or misled by reported AWPs cannot be squared with the fact that the state and federal governments knew that AWPs were substantially higher than actual acquisition costs.[31] This defeats all of the State's claims that turn in any way on establishing deception or intent to defraud, mislead or deceive.

B. The State's Allegations Are Not Pled With Sufficient Particularity and Should Be Dismissed for That Reason Alone

In addition to failing to account for the longstanding public record concerning the nature of AWPs, the State's complaints are based on sweeping, conclusory allegations that fail to identify critical facts such as which drugs the State seeks to place at issue, which markets they were sold in, which government programs paid for them and which AWPs or other pricing

[31] As discussed in footnote 4 above, under New York law such public record evidence can be "read into the complaint" and considered on a motion to dismiss even (and especially) if it contradicts the allegations of the Complaint.

information were the basis for the government's reimbursement. The State's complaints fail to satisfy the basic particularity requirements of New York's pleading rules, and fail to inform the defendants and the Court whether this case involves a small number of drugs sold primarily to physicians, hundreds of drugs sold in multiple providers settings, or some number of drugs in between.

Recognizing the importance of holding plaintiffs to their pleading burdens in complex litigation like this, the federal judge presiding over the consolidated AWP proceedings in the District of Massachusetts (to which this case was transferred prior to remand) has held that broad, non drug-specific allegations are insufficient. The court in those proceedings held that plaintiffs were required to make specific allegations on a drug-by-drug basis in order to proceed with AWP claims for any particular drug. *See In re Pharmaceutical Industry Average Wholesale Price Litigation*, 263 F.Supp. 2d 172, 194 (D. Mass. 2003). New York law requires the State to be held to at least the same pleading specificity requirements.

In order to comply with basic pleading requirements under New York law:

> Statements in a pleading shall be sufficiently particular to give the court and parties notice of the transactions, occurrences, or series of transactions or occurrences, intended to be proved and the material elements of each cause of action or defense.

CPLR § 3013.[32] A pleading is insufficient under CPLR § 3013 if it relies on conclusory allegations pertaining to any element of the claim or defense.[33]

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[32] *See generally Sinacore v. State of New York*, 176 Misc. 2d 1, 671 N.Y.S.2d 896 (Ct. Cl. 1998) (holding that allegations should give notice of the relevant transactions and occurrences and set forth each material element of the claim); *Confidence Transp. Inc. v. Buck*, 218 A.D.2d 837, 630 N.Y.S.2d 804 (3d Dep't 1995) (same).

[33] *See Dibble v. Board of Coop. Educ. Serv.*, 103 A.D.2d 1026, 478 N.Y.S.2d 412 (4th Dep't 1984) (dismissing complaint and granting summary judgment because plaintiff "wholly failed" to set forth transactions or occurrences alleged); *Willis v. Kepner*, 109 A.D.2d 950, 951, 486 N.Y.S.2d 440, 441 (3d Dep't 1985) ("It is

Moreover, "[w]here a cause of action or defense is based upon misrepresentation, fraud, mistake, willful default, breach of trust or undue influence, the circumstances constituting the wrong shall be stated in detail." CPLR § 3016(b).[34] Accordingly, when pleading a cause of action based on fraud, each element of fraud must be supported by specific facts and circumstances sufficient to satisfy the pleading requirements of CPLR 3016(b).[35]

The proper consequence of not specifying detailed allegations of fact in support of a cause of action based in fraud is dismissal. *See Callas v. Eisenberg*, 192 A.D.2d 349, 350, 595 N.Y.S.2d 775 (1st Dep't 1993). As one New York Court stated "[t]he test is whether the pleading[] give[s] adequate notice to the court and the adverse party of the transactions or occurrences intended to be proved." *Two Clinton Square Corp. v. Friedler*, 91 A.D.2d 1193, 1194, 459 N.Y.S.2d 179 (4th Dep't 1983); *see also, Foley v. D'Agostino*, 21 A.D.2d 60, 64, 248 N.Y.S.2d 121 (1st Dep't 1964). The complaints in these cases should be dismissed for failure to do exactly that.

1. The State Fails to Specify Which of Defendants' Drugs Are At Issue

Each of the complaints contain only one or two paragraphs that set forth any allegations about any specifically identified drugs. Of the few drugs identified by name in each of the complaints, all of them are among the small subset of prescription drugs that are sold to and

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essential that the statements in the pleadings enable the court and defendants to determine what activities plaintiffs are complaining of").

[34] Counts One (deceptive acts and practices), Two (repeated or consistent fraud in conducting business) and Five (obtaining public funds by false statements) are plainly "based upon misrepresentation or fraud." Count Three and Four, the commercial bribery and anti-kickback regulation allegations also fall within the purview of § 3016(b) as they are based on "breach of trust" or "undue influence."

[35] *See Cohen v. Houseconnect Realty Corp.*, 289 A.D.2d 277, 734 N.Y.S.2d 205 (2d Dep't 2001); *Glassman v. Catli*, 111 A.D.2d 744, 745, 489 N.Y.S.2d 777 (2d Dep't 1985); *Bramex Assoc., Inc. v. CBI Agencies, Ltd.*, 149 A.D.2d 383, 540 N.Y.S.2d 243 (1st Dep't 1989).

administered directly by physicians and covered by Medicare Part B. See Aventis Complaint at ¶ 25 (naming two Medicare Part B covered drugs); GSK Complaint at ¶ 25 (naming five Medicare Part B covered Drugs); Pharmacia Complaint at ¶¶ 24-25 (naming seven Medicare Part B covered drugs).

With respect to drugs administered by physicians, as discussed above, the State can bring no claims under EPIC (which does not cover physician-administered drugs) or under New York's Medicaid program (which reimburses for such drugs at actual cost, irrespective of AWPs). Thus, any claims the State seeks to make with respect to the few physician-administered drugs actually identified in its complaints can only be made on behalf of Medicare Part B co-payors.

Despite purporting to bring a number of claims on behalf of the New York Medicaid and EPIC programs, the State does not clearly specify in the complaints whether it seeks to make such claims for any drugs ***other than the Medicare Part B drugs*** it specifically identifies by name, let alone does it specify which additional drugs (if any) may be the subject of the State's claims. Obviously, because the complaints fail to identify more than a few drugs, they also fail to allege specifically what (if anything) the defendants are alleged to have done with respect to any of the unnamed drugs. The State clearly cannot proceed against any defendant without specifying which drugs it seeks to place at issue and pleading the essential facts about each such drug that are necessary to state any claim.

Specificity with respect to which drugs are being placed at issue is critically important. Different drugs are priced and marketed in different ways, are sold primarily in different markets (e.g. the physician-administered market vs. the retail pharmacy market), and are reimbursed in

different ways by different government programs. New York Medicaid's own distinction between physician administered drugs (which it reimburses at actual cost) and pharmacy-dispensed drugs (which it reimburses at AWP-12%) is a clear recognition of the differences between these two markets. The State cannot reasonably contend that every drug sold at any discounted price in any market for an undefined period of time should be the subject of its claims. In fact, it is not clear from the complaints that the State is taking that position. The point is that defendants do not know what drugs the State seeks to place at issue. Under New York pleading rules, the State cannot proceed with any claims for any drugs it has not (among other things) named in the complaints.

2. With Regard to All Drugs Named in the Complaints, the Claims Cannot Proceed Without Additional Specific Allegations that Inform the Defendant of The Nature of the State's Claims

Perhaps in an effort to obscure the fact that the government was aware of the public record materials about AWPs, the complaints are also remarkably vague about the core issue of what reported pricing information allegedly deceived New York Medicaid, New York EPIC and federal Medicare officials, and exactly how the government was deceived. With respect to Pharmacia, the State alleges that the company reported an "average wholesale price" for its prescription drugs. Pharmacia Complaint ¶ 15. Yet the State ***says absolutely nothing about what Pharmacia's AWPs were for any drug*** (including even the few Medicare Part B drugs named in the complaint) or precisely how any AWP deceived the State or the federal government at any time.

With respect to Aventis and GSK, the complaints initially allege that the companies reported a "wholesale acquisition cost" ("WAC") for their prescription drugs to commercial

price reporting services. GSK and Aventis Complaints ¶ 15. They then allege that ***the reporting services*** added a "standard markup" to WAC, that those commercial reporting services reported the "marked-up" amount as the "average wholesale price" ("AWP"), and that the Medicaid, Medicare and EPIC programs were deceived by the marked-up AWPs reported by the commercial price reporting services. GSK and Aventis Complaints ¶¶ 16, 20, 22, 28-29; 33-35. Again, however, the State ***says absolutely nothing about what the AWPs (or WACs) were for any drug*** (including even the few Medicare Part B drugs named in the complaints), or about precisely how the AWPs deceived the State or federal government at any time.

In addition, for Aventis and GSK, the State alleges that prior to 2000 and 2001 respectively, these defendants "reported ***amounts*** to the price reporting services, ***using various labels***, that either were average wholesale price or its equivalent, which the price reporting services reported as 'average wholesale price,' ***or were another measure of cost or price*** that the ***price reporting services*** used as a basis for determining the average wholesale price ***that they reported"*** for GSK's and Aventis's drugs. GSK and Aventis Complaints ¶ 17 (emphasis added). Other than making it clear that the State is complaining for this earlier time period about prices calculated and reported by the price reporting services, it is impossible to determine from these allegations what "measures of cost or price" were allegedly reported using what "labels" by the defendants. These, of course, are critical matters in a case about allegedly deceptive price reporting. When these vague allegations are added to the State's failure even to identify exactly what drugs it is complaining about, its failure to identify any specific AWP or other allegedly deceptive price for any such drug, and its failure to plead facts about how State or Medicare

officials were deceived by any AWP or other specific pricing information, it becomes clear that the State's complaints are fatally defective for their lack of specificity.

Similarly, the State broadly alleges that the defendants "marketed the spread" to physicians and other providers in order to cause providers to change their prescribing decisions so that defendants could increase their market shares. Yet the complaints refer to the "spread" one way in paragraph 24 of the GSK and Aventis complaints and paragraph 23 of the Pharmacia complaint (i.e., as the difference between the amount a provider pays for a drug and the amount a healthcare program reimburses for it), and in another way in the very next paragraph of each Complaint (i.e., the difference between what providers pay "middlemen" and what those middlemen list as their catalogue price). This inconsistency leaves the defendants to guess about which "spreads" are being complained about. Finally, nowhere in the complaint does the State even specify the time period for which it seeks redress.

Consistent with well-established requirements for specificity in cases such as this (cited above), at a minimum, the State should be required to allege, for each drug for which it seeks to assert claims:

- the name of each drug it seeks to place at issue;
- the drug's AWP, WAC or "other pricing information" that the State alleges was deceptive or misleading;
- whether and why any such AWP, WAC or other specifically identified "other pricing information" was deceptive or misleading, and what specific misrepresentations were made with respect to that AWP, WAC or other pricing information by each defendant;
- what "spreads" the State is complaining about and why such "spreads" were improper or excessive;

- whether and how such "spreads" were allegedly "marketed," and to what provider types (e.g., physicians, retail pharmacists or others), in order to improperly increase defendants' market share;

- the relevant time period

Because the current complaints do not contain the specific allegations required for any of defendants' drugs, they should be dismissed for this reason alone.

C. The State Has Failed To Plead A Claim Under General Business Law Section 349 for Deceptive Acts and Practices

In addition to suffering from a fatal lack of particularity, the State's First Cause of Action fails to state a claim under New York General Business Law ("GBL") § 349. There are three crucial elements for a claim under GBL § 349. First, plaintiff must show that the challenged act or practice was consumer oriented. Second, plaintiff must show that the challenged act was misleading in a material way. Third, plaintiff must show that it suffered injury as a result of the deceptive act. *See Stutman v. Chemical Bank*, 95 N.Y.2d 24, 29, 709 N.Y.S.2d 892, 895 (2000); *Oswego Laborers' Local 214 Pension Fund v. Marine Midland Bank*, 85 N.Y.2d 20, 623 N.Y.S.2d 529 (1995). The misconduct generally alleged -- that the defendants provided "inflated" information about AWPs, WACs and "other" pricing information to third-party price reporting services which State and federal officials then used to set reimbursement rates for Medicaid, Medicare and EPIC -- satisfies none of these requirements. In addition, the State cannot invoke § 349 to sue for its own alleged losses.

1. Defendants' Conduct Was Not Misleading

Given the well-established understanding in the industry and the government that AWPs were "undiscounted list prices" or "sticker prices" that often bore no relationship to market prices, the State cannot prevail on any claim that the various price reporting activities of the

defendants were "misleading in a material way." As discussed above, the public record clearly establishes that the government programs set their various reimbursement rates on the basis of AWPs reported by the pricing services, despite knowing full well that reported AWPs were often substantially higher than actual acquisition costs. This was a deliberate policy choice that has been subject to public debate literally for decades. Whatever information the defendants transmitted to the price reporting services does not alter the fact that the government payors knew that by using AWP as a pricing benchmark, even if discounted, they were often reimbursing providers more than the providers paid for the drugs. In light of the undisputed regulatory history of AWP, the defendants' alleged conduct simply cannot be deemed misleading in a material way. *See Zuckerman v. BMG Direct Mktg., Inc.*, 290 A.D.2d 330, 331, 737 N.Y.S.2d 14, 15 (1st Dep't 2002) (rejecting § 349 claim because "as a matter of law, a disclosure that a specified amount will be charged for shipping and handling cannot cause a reasonable consumer to believe that such amount necessarily is equal to or less than the seller's actual shipping and handling costs.")

2. Defendants' Conduct Was Not Consumer Oriented

Article 22-A of the General Business Law, which includes Section 349, is entitled "Consumer Protection from Deceptive Acts and Practices" and provides, in relevant part, that "[d]eceptive acts or practices in the conduct of any business, trade or commerce or in the furnishing of any service in [New York] are . . . unlawful." The statute's primary concern is with the consumer, and thus, the threshold requirement of GBL § 349 is that the conduct complained of be "consumer-oriented." *Cruz v. Nynex Info. Resources*, 263 A.D.2d 285, 290, 703 N.Y.S.2d

103, 107 (1st Dep't 2000) (citing authority). A federal court, having surveyed the case law, described GBL § 349 as follows:

> The typical violation contemplated by [GBL § 349] involves an individual consumer who falls victim to misrepresentations made by a seller of consumer goods . . . [T]he consumer oriented nature of the statute is evidenced by the remedies it provides. [The statute] provides parties with the opportunity to receive the greater of actual damages or $50. The New York cases where plaintiffs have recovered under [the statute] further reflect its consumer orientation since they uniformly involve transactions where the amount in controversy is small.

Genesco Entertainment v. Koch, 593 F. Supp. 743, 751-52 (S.D.N.Y. 1984) (footnotes omitted).[36]

The State does not plead, and cannot show, that the defendants' acts were "consumer oriented." Under New York law, "the term 'consumer' is consistently associated with an individual or natural person who purchases goods, services or property primarily for 'personal, family or household purposes.'" *Cruz*, 263 A.D.2d at 289, 703 N.Y.S.2d at 106 (citing various New York statutes). In making the required *prima facie* showing that conduct is consumer oriented, the State must show that the acts or practices complained of are "directed to consumers . . ." *Cruz*, 263 A.D.2d at 290, 703 N.Y.S.2d at 107. Nowhere in the complaints does the State allege that defendants' alleged price reporting is "directed to consumers."

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[36] *See Cruz*, 263 A.D.2d at 290, 703 N.Y.S.2d at 107 (dismissing GBL claim arising from the sale of advertising space in a phone book because conduct complained of was directed at businesses and thus did not fall within the statute protecting consumers); *New York Univ. v. Continental Ins. Co.*, 87 N.Y.2d 308, 321, 662 N.E.2d 763, 770, 639 N.Y.S.2d 283, 290 (1995) (dismissing § 349 claim because defendant's acts in selling an insurance policy and handling claims were not consumer-oriented, despite allegations of numerous instances of similar bad-faith practices respecting policyholders nationwide); *Banc of Am. Comm. Fin. Corp. v. Issacharoff*, 188 Misc. 2d 790, 798, 728 N.Y.S.2d 861, 867 (Sup. Ct. 2000) (dismissing claim concerning loan as not consumer-oriented, even though loan used standard form that could be replicated with other customers); *P. Kaufmann, Inc. v. Americraft Fabrics, Inc.*, 232 F. Supp. 2d 220, 225-26 (S.D.N.Y. 2002) (dismissing § 349 claim as not consumer-oriented because no allegation of harm to consuming public); *see generally Stutman*, 95 N.Y.2d at 29, 709 N.Y.S.2d at 895 ("the deceptive practice must be 'likely to mislead a reasonable *consumer* acting reasonably under the circumstances.'") (quoting *Oswego*, 85 N.Y.2d at 26 (emphasis added)).

Pharmaceutical manufacturers' reporting of price information to commercial price reporting services is not conduct directed to individuals or natural persons and therefore is not directed at the "consuming public at large." *New York Univ.*, 87 N.Y.2d at 321, 639 N.Y.S.2d at 290-91. The defendants' conduct was directed at another business -- the price publishing services -- which were sometimes consulted by the government to set reimbursement rates. Nowhere do the complaints allege that the consuming public reviews or relies on the commercial price publishing services. Instead, the publishing service "reports these average wholesale prices in a computer file which it sends to the New York Department of Health." Complaints ¶ 16. Under these circumstances, the nexus between the challenged conduct and the consumer is too tenuous to support a Section 349 claim. *See Cruz*, 263 A.D.2d at 291 (insufficient link between alleged harm to businesses and consuming public at large to state § 349 claim); *P. Kaufmann*, 232 F. Supp. 2d at 226 (same).

To the extent that the State argues that the defendants' price reporting, although not directed at consumers, could "affect consumers," the State's allegations still fail to fall within the statute. Use of AWPs by New York's Medicaid and EPIC programs do not "affect consumers." Due to the co-payment structure under those programs, the individual beneficiaries are not affected even if the State's own reimbursement payments were inflated as alleged. The amount of the co-payments for Medicaid participants (which are flat) and EPIC participants (which are fixed amounts on a sliding scale) are not based on a percentage of the reimbursement paid for each drug. Consequently, the price of pharmaceuticals reimbursed under these programs does not impact the consumers' co-payments.

To the extent claims are based on co-payments by New York citizens under the Medicare Act, those too fail to fall within Section 349. There, the gravamen of the claim is that defendants misled the federal government into setting excessive reimbursement rates that incidentally resulted in higher co-payments by beneficiaries. *See* Complaints ¶ 24 (focusing on the amount that Medicare reimburses). However, harm to the public that is merely incidental cannot sustain a claim under section 349. *See Fashion Boutique of Short Hills. v. Fendi*, No. 91 Civ. 4544 (MGC), 1992 WL 170559, at *4 (S.D.N.Y. 1992) (dismissing § 349 claim where primary harm alleged was to plaintiff's business; harm to consumers only "incidental," despite allegations that defendant made false statements to plaintiff's potential customers).

3. Section 349 Does Not Authorize The State To Sue For Its Own Losses

To the extent the State itself seeks to recover for payments ***it*** made under Medicaid and EPIC,[37] the State itself cannot be considered a consumer for purposes of Section 349. The statute authorizes the Attorney General to sue for "restitution," ***"in the name and on behalf of the people of the State of New York,"*** General Business Law § 349(b) (emphasis added). "Restitution" refers to "***consumers***' rights to restitution." *State v. Princess Prestige Co.*, 42 N.Y.2d 104, 108, 397 N.Y.S.2d 360, 362 (1977) (construing Executive Law 63(12)) (emphasis added). Other provisions of the statute also make clear that under "New York law, the term 'consumer' is consistently associated with ***an individual or natural person*** who purchases goods, services or property primarily for personal, family or household purposes." *Cruz*, 263

[37] The State makes no payments with respect to Medicare.

A.D.2d at 291, 703 N.Y.S.2d at 107 (emphasis added, citations omitted).[38] Accordingly, Section 349 does not provide a basis for the Attorney General to sue to recover the ***State's*** claimed losses (as opposed to losses to consumers). *See Genesco Entertainment Inc. v. Koch*, 593 F. Supp. 743, 751 (S.D.N.Y. 1984) (§ 349 "wears its purpose on its face; it is entitled 'Consumer Protection from Deceptive Acts and Practices'").[39]

4. Defendants' Alleged Conduct Did Not Cause the Alleged Injuries

To assert a claim under GBL § 349, "[t]he plaintiff . . . must show that the defendant's 'material deceptive act' ***caused the injury***.'" *Stutman*, 95 N.Y.2d at 29, 709 N.Y.S.2d at 895 (emphasis added) (quoting *Oswego*, 85 N.Y.2d at 26, 623 N.Y.S.2d at 533). The State has not pled any facts that satisfy this element, and the broad and general allegations it makes show the contrary to be true. The alleged over-reimbursement for unspecified pharmaceuticals were not caused by the defendants' price reporting, but by multiple and important intervening acts of others (including the government itself).

In the case of Aventis and GSK, the State does not even allege that it used the pricing information reported by the defendant. Instead, it alleges that defendants reported WAC to third-party price reporting services, who themselves added a markup that converted WAC to AWP

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38 *See* General Business Law § 399-c(1)(a) ("The term 'consumer' shall mean a natural person residing in this state); General Business Law § 399(p)(1)(c) ("consumer means a ***natural person*** who is solicited to purchase, lease or receive a good or service for personal, family or household use") (emphasis added).

39 Nor can the Attorney General sue under Section 349(h), the private right of action provision. There is no indication that by adding this subsection in 1980 to create a private right of action for "persons" injured by a violation of the statute, the Legislature intended to provide a basis, in addition to Section 349(b), for suit by the Attorney General. It is well established that "in common usage, the term 'person' does not include the sovereign, [and] statutes employing the [word] are ordinarily construed to exclude it." *Will v. Michigan Dep't of State Police*, 491 U.S. 58, 64 (1989) (internal quotation marks and citation omitted); McKinney's Cons. Laws of N.Y., Book 1, Statutes § 115 ("a statute does not apply to the State . . . unless it is specifically mentioned therein or included by necessary implication"). Moreover, the legislative history of subsection (h) establishes that the Legislature intended to limit the new private right of action to "individuals" and "consumers," neither of which describes the State. *See* "Memorandum in Support of Legislation;" Governor's Program Bill 1977 Memorandum.

(which, in turn, the State used in setting its reimbursement rates for pharmacy-dispensed drugs). GSK and Aventis Complaints ¶¶ 16, 20, 22, 28-29; 33-35. Or, the State alleges, these defendants at various times reported other pricing information to the reporting services, which the reporting services in turn converted to AWPs. *Id.* at ¶ 17. Either way, the State acknowledges that intervening decisions by the price reporting services produced the AWPs on which the government relied. In the case of Pharmacia, the State alleges that the defendant reported AWPs directly to the price reporting services, which services were then consulted by the government to set reimbursement rates. In each of these reporting permutations, however, the State is alleging that the defendants reported pricing information to third-party publishers, and it was the ***third-party publishers*** on whom the government relied.[40]

Moreover, there were other critical intervening acts in the casual chain:

(1) ***Physicians and pharmacists*** (who allegedly got discounts) -- and not the defendants -- made claims for reimbursement to Medicare, Medicaid and EPIC.

(2) Most importantly, the ***government*** decided whether to use AWP in setting its reimbursement rates. Ultimately, the amount paid by the State's Medicaid program, by EPIC and by Medicare (and Medicare 20% co-payors) was most directly determined by the reimbursement formula that the federal or New York state government decided to adopt for that program. The defendants did not have any role in setting the reimbursement rate or the amount of any co-payments. Those decisions were made by the government. The alleged injuries, therefore, were caused by the intervening acts of other parties, including the government -- not by the defendants.

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[40] The State did so despite its statutory authority to obtain pricing information directly from the defendants.

At common law, a plaintiff suing for fraud must show that its "damage flowed from the fraud as the proximate and not the remote cause." *Brackett v. Griswold*, 112 N.Y. 454, 469 (1889). The same principles of proximate causation and directness of injury apply to statutory causes of action such as the claims asserted by the State in this case under Section 349. *See, e.g., A.O. Fox Memorial Hospital v. American Tobacco Co.*, 302 A.D.2d 413, 754 N.Y.S.2d 368 (2d Dep't 2003) (affirming dismissal under remoteness doctrine of claims under Section 349 by hospitals against tobacco companies for costs incurred as a result of patients with tobacco-related health problems); *Eastern States Health & Welfare Fund v. Philip Morris, Inc.*, 188 Misc. 2d 638, 729 N.Y.S.2d 240 (Sup. Ct. N.Y. Cty. 2000) (dismissing under remoteness doctrine claims under Section 349 by plaintiff health and welfare employee benefit and trust funds against tobacco companies for damages incurred through payments on behalf of beneficiaries with tobacco-related health problems).[41]

For each of the reasons set forth above, the Deceptive Acts and Practices claim should be dismissed.

D. The State Has Failed to State a Cause of Action Under Executive Law 63(12) For "Repeated and Persistent Fraud"

The State's Second Cause of Action asserts a claim against the defendants for "Repeated and Persistent Fraud" pursuant to Executive Law 63(12). That section authorizes the Attorney General to seek relief:

> Whenever any person shall engage in repeated fraudulent or illegal acts or otherwise demonstrate persistent fraud or illegality in the

[41] Because there is some authority for the contention that proximate causation has been relaxed, although not eliminated, for § 349 claims, the United States Court of Appeals for the Second Circuit recently certified the issue of the applicability of the remoteness doctrine to claims brought under § 349. *See Empire Blue Cross and Blue Shield v. Philip Morris USA Inc.*, 344 F.3d 211, 219-21 (2d Cir. 2003), and the New York Court of Appeals has accepted the certification, 2003 WL 22455503 (Mem.) (2003).

> carrying on, conducting or transaction of business, the attorney general may apply . . . for an order enjoining the continuance of such business activity or of any fraudulent [and] or illegal acts directing restitution and damages . . . .[42]

While somewhat unclear from the complaints, it appears that the State is invoking Executive Law 63(12) in this claim to address the same acts that form the basis for the complaints' first count under GBL § 349, and perhaps also as a separate cause of action directly under Executive Law 63(12). Complaints ¶¶ 41, 42. Either way, this cause of action, like the first one, suffers from a fatal lack of specificity and from all of the same infirmities as the GBL § 349 claim discussed above.

As explained above, the State's contention that the New York Medicaid and EPIC Programs and Medicare were victims of a fraud that deceived them into reimbursing at AWP-based rates is contradicted by the relevant regulatory history. Furthermore, as discussed above, any alleged governmental overpayments were caused by multiple intervening acts, including the government health care programs' own reimbursement decisions, and not the defendants' allegedly fraudulent conduct.[43]

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[42] The definition of "fraud" under the Executive Law is defined to include "any device, scheme or artifice to defraud and any deception, misrepresentation, concealment, suppression [or] false pretense..." Executive Law 63(12).

[43] In addition, to the extent the State is seeking to bring a fraud claim directly under § 63(12) for recovery of its own Medicaid and EPIC payments without reference to GBL §349 or any other statute, it must plead all the elements of common law fraud, which it fails to do. For example, it must plead that the State relied on defendants' alleged misrepresentations, and that such reliance was justifiable. *Vermeer Owners, Inc. v. Guterman*, 78 N.Y.2d 1114, 1116, 578 N.Y.S.2d 128, 129 (1991); *Abrahami v. UPC Constr. Co.*, 224 A.D.2d 231, 232-33, 638 N.Y.S.2d 11 (1st Dep't 1996). A plaintiff may not "shut his eyes" to a potential fraud and later claim that the defendant induced him to believe certain facts, the truth or falsity of which he could have earlier ascertained. *Ittleson v. Lombardi*, 193 A.D.2d 374, 376, 596 N.Y.S.2d 817, 819 (1st Dep't 1993) (plaintiff's fraud claim should have been dismissed because plaintiff had "means available to him for discovering 'by the exercise of ordinary intelligence'" the true facts). Here, in light of the irrefutable history set forth above, the State does not allege and could not prove justifiable reliance.

E. The Complaints Fail To State A Claim For Repeated and Persistent Illegal Conduct Constituting Commercial Bribery.

In its Third Cause of Action, the State alleges that defendants violated Executive Law § 63(12) by engaging in repeated and persistent commercial bribery in violation of Penal Law § 180.00. The State merely recites the commercial bribery statute and refers generally to the "acts and practices described above" in the complaints. The cited statute, New York Penal Law § 180, provides that

> A person is guilty of commercial bribery in the second degree when he confers, or offers or agrees to confer, any benefit upon any employee, agent or fiduciary without the consent of the latter's employer or principal, with intent to influence his conduct in relation to his employer's or principal's affairs.

In order to violate the statute, a person must (1) confer or offer to confer any benefit; (2) on a fiduciary; (3) without the consent of the fiduciary's principal; (4) with intent to corruptly influence his conduct in relation to his principal's affairs. *People v. Tuttle*, 45 A.D.2d 750, 356 N.Y.S.2d 652 (2d Dept 1974).

There is only a single paragraph in the complaints that appears to relate to this claim, which reads:

> In New York, physicians have fiduciary obligations to their patients, including the duty to use their independent professional judgment in making treatment decisions and not to accept any consideration to alter that judgment. [Defendants] create[] and market[] the spread on [their] prescription drugs to New York doctors without the consent or knowledge of their patients and with intent to influence the physicians' choice of drugs to administer or prescribe to their patients. Complaints ¶ 36.[44]

[44] The complaints' commercial bribery allegations are specifically limited by the text of Paragraph 36 to drugs marketed to physicians -- and not to drugs sold to retail pharmacists or other providers. Furthermore, the complaints do not allege that pharmacists have any fiduciary obligations to their customers with which defendants sought to interfere, a necessary pre-requisite to alleging a claim for commercial bribery.

This allegation provides no specifics whatsoever. It is quite remarkable that the New York Attorney General can allege that the defendants violated the commercial bribery statute (a Penal Law) without identifying a single alleged bribe, without identifying which drugs were allegedly involved and what "spreads" were allegedly marketed to alter the physicians' choice of drugs to administer, without identifying any physician the defendants allegedly bribed or sought to bribe, and without providing any particulars at all about any alleged bribe. This cause of action should be dismissed for lack of specificity alone.

On the merits, the State's "repeated and persistent" commercial bribery claims -- which are directed to marketing to physicians -- cannot apply to drugs that are reimbursed by either EPIC or the New York Medicaid program. EPIC does not even reimburse for drugs sold to and administered by physicians; it only covers drugs dispensed in pharmacies. Complaints ¶ 13. And the New York Medicaid program reimburses physician-administered drugs based on the actual acquisition cost to the physician. N.Y. Soc. Serv. Law § 367-a(9)(a). Thus, there can be no "spreads" to market when the doctor is being reimbursed by New York's Medicaid program.[45]

Given these provisions of New York's Medicaid and EPIC programs, the State's commercial bribery allegations can apply only to Medicare Part B drugs sold to doctors who administered this narrow class of drugs to Medicare patients who made co-payments in New York state. Only for this narrow subset of Medicare Part B drugs does the doctor buy the drug and submit a reimbursement claim that is paid based on AWPs. Yet the State's commercial

[45] Similarly, if a doctor is merely prescribing a drug (but not buying it and making a reimbursement claim for it) the doctor cannot possibly be paying less and submitting a reimbursement claim for more -- so there can be no "spreads" to market to the doctor to influence his choice of drug and there can be no "commercial bribery" under the State's theory.

bribery claims must fail even as to this narrow class of Medicare Part B drugs sold to doctors, for two reasons: (1) the State has not alleged interference with a relevant fiduciary duty; and (2) the State has not adequately alleged that the defendants (as opposed to the government) have conferred or offered to confer a benefit on any physician.

The purpose of the commercial bribery statute is to prohibit conferring a benefit with the intent to induce another to act corruptly ***in the context of a fiduciary relationship***.[46] Under New York law, physicians do not have a general fiduciary duty covering all aspects of their relationship with patients. Physicians have a duty to provide treatment to patients consistent with the appropriate standard of care applicable to the profession. *Arias v. Flushing Hosp. Med. Center*, 300 A.D.2d 610, 753 N.Y.S.2d 518 (2d Dep't 2002). If a patient does not receive reasonable care from a doctor, the patient has adequate redress in the courts for any injuries through a professional liability action. *See, e.g.*, *Anderson v. Lamaute*, 306 A.D.2d 232, 233, 761 N.Y.S.2d 87, 89 (2d Dep't 2003) (elements of proof of medical malpractice action are a deviation or departure from accepted practice and evidence that such departure was proximate cause of the injury).

Here, the State has made no allegation that the defendants intended to influence any doctor to act in a manner inconsistent with the patient's interests, or that any doctor did so. The State has not alleged that a single doctor chose a drug that was inferior, from a patient care perspective, to another drug. The State's mere allegation that the defendants intended to influence a doctor to choose one drug over another, because of a financial incentive to the doctor,

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[46] *See Schiff v. Kirby*, 22 Misc. 2d 786, 790, 194 N.Y.S.2d 695, 701 (Sup. Ct. Westchester Cty. 1959) (purpose and intent of commercial bribery statute is to forbid corrupt influence of agents, employees and servants); *Stat Medical Services, Inc. v. Daughters of Jacob Geriatric Ctr., Inc.*, 797 F. Supp. 253 (S.D.N.Y. 1993) (failure to show that plaintiff had conferred benefit with intent to influence conduct *in favor of plaintiff* resulted in dismissal of affirmative defense of commercial bribery).

is insufficient to show interference with the doctor's fiduciary duty of care for purposes of a Commercial Bribery allegation. Under New York law, so long as a doctor acts in a way that is consistent with a professional standard of care, the doctor does not breach a fiduciary duty to a patient merely by choosing one medically appropriate drug over another, even if financial considerations factor into the decision.[47] Because that is, at most, what the State alleges, it has not adequately alleged that defendants interfered with or attempted to interfere with a fiduciary relationship as is necessary to state a commercial bribery claim.

Finally, the commercial bribery claims must fail because the State has not adequately pled that the ***defendants*** conferred or agreed to confer a benefit upon any doctor in an effort to influence his choice of drug. As outlined in the Regulatory and Legislative Background section of this Memorandum, the federal government chose to implement a Medicare reimbursement scheme that reimbursed doctors more than the doctors paid to acquire oncology and other Medicare Part B drugs knowing that it was doing so, and choosing to do so in order to compensate oncologists for other costs associated with administering those drugs. To the extent this additional payment (or "spread") can be considered a "benefit" for purposes of the

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[47] To the extent that any doctor altered his or her treatment of patients in a clinically neutral way in order to take advantage of the widely known fact that the government may reimburse at a higher rate than what the doctor paid, that doctor is not breaching a fiduciary duty. In *Weiss v. CIGNA Healthcare, Inc.*, 972 F.Supp 748, 752 (S.D.N.Y. 1997), participants in an employee welfare benefit plan brought action against a health maintenance organization ("HMO") which had been retained by their employer, alleging various "breach of fiduciary duty" claims. The defendants claimed, *inter alia* that the HMO compensated their participating physicians through "capitation" payments and "withholds," whereby the physician would receive financial bonuses if they kept their referral and hospitalization rates below a certain level. The plaintiffs asserted that this payment scheme created a "direct conflict of interest in the exercise of the [physicians] medical judgment and causes the breach of the fiduciary duty owed by the participating physicians to the plaintiff[s]." Judge Stein dismissed the breach of fiduciary duty claim, holding that it could not be sustained even if the physician breached an ethical duty to provide necessary care. *Weiss*, 972 F.Supp at 752; *see, also D.A.B. v. Brown*, 570 N.W.2d 168, 171 (Minn. Ct. App. 1997) (holding that the proper cause of action against physicians taking kickbacks is in medical malpractice, not breach of fiduciary duty); *Neade v. Portes*, 739 N.E.2d 496, 506 (Sup. Ct. Ill. 2000) (breach of fiduciary claim against physician for failure to disclose financial incentives dismissed).

commercial bribery statute, it was the ***federal government*** that conferred the benefit, not the defendants. *People v. Teitelbaum*, 138 A.D.2d 647, 649, 526 N.Y.S.2d 230, 232 (1st Dep't 1988) (affirming dismissal of action against an alleged accomplice to commercial bribery because court found she did not participate in conferring a benefit).[48]

For all of these reasons -- lack of specificity, failure to allege interference with the physician's duty to provide quality patient care, and failure to allege facts that show that defendants (as opposed to the government) conferred a benefit on physicians -- the complaints fail to state a claim for commercial bribery and the State's Third Cause of Action must be dismissed.

F. The Claims for Repeated and Persistent Medicaid Kickbacks and Fraud Must Be Dismissed

For its Fourth Cause of Action, the State alleges that the defendants repeatedly and persistently violated Executive Law § 63(12) by violating an "Unacceptable Practice" regulation promulgated by the New York Department of Health, 18 N.Y.C.R.R. § 515.2(b)(5), which governs claims relating to Medicaid only.[49] That regulation, which is quoted in part in the complaint, provides that:

> [u]nless the discount or reduction in price is disclosed to the client and the department and reflected in a claim" it is impermissible to "offer[] or pay either directly or indirectly any payment (including any kickback, bribe, . . . rebate or discount), whether in cash or in kind, in return for purchasing, . . . ordering or recommending any

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48 The defendants are, at bottom, alleged to have educated doctors about the "spreads" that arose when Medicare chose to reimburse based on AWPs that were higher than actual acquisition costs. It is inconceivable that informing doctors of the reimbursement amounts expected to be paid by the government, and the resulting "spreads," which are widely known to exist, can constitute a commercial bribe. *See Southmark/Envicon Capital Corp. v. United Airlines, Inc.*, 132 Misc. 2d 586, 589, 505 N.Y.S.2d 491, 494 (Sup. Ct. N.Y. Cty. 1986) (dismissing commercial bribery count because benefits conferred were generally known and available to the public).

49 Count Four of the complaints is specifically limited to claims relating to the New York Medicaid Program.

> medical care, services or supplies for which payment is claimed under [Medicaid].

In this Cause of Action, the State merely quotes this regulation, generally refers back to the "acts and practices described above" in the complaints, and alleges a violation of the regulation. As far as defendants can tell, the only paragraph in the complaints setting forth "acts and practices" that relate to this claim is paragraph 30. There, the State alleges that the defendants fraudulently created and marketed the "spread" on its drugs to New York pharmacists, without saying which drugs and without saying what the "spread" is for any drug[50] The State alleges that defendants marketed the "spread" to pharmacists in order to induce them to recommend defendants' drugs to doctors and Medicaid recipients, and that the amount of the "spreads" were not disclosed to the States and to Medicaid recipients. Complaints ¶ 30.

This claim (1) by its terms, applies only to Medicaid reimbursements (not Medicare or EPIC), and (2) is being asserted by the State only with respect to sales of drugs to pharmacists (not to physicians).[51] Even as to such sales, however, the claim should be dismissed because (a) it makes no economic sense, and (b) it is defeated by the fact (which is not disclosed in the complaints) that, pursuant to EPIC program requirements, the defendants provide pricing data to the State that reveals the information that the State is contending defendants fraudulently concealed.

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50 As noted above, the complaints refer to the "spread" one way in paragraph 24 of the GSK and Aventis Complaints and paragraph 23 of the Pharmacia complaint (i.e., as the difference between the amount a provider pays for a drug and the amount a healthcare program reimburses for it), and in another way in the very next paragraph of each Complaint (i.e., the difference between what providers pay "middlemen" and what those middlemen list as their catalogue price) -- leaving the defendants to guess about which "spreads" are being complained about.

51 The State could not possibly make this claim with respect to physicians who submit Medicaid claims, because they are reimbursed under New York Medicaid law at their actual cost (without regard to the drug's AWP), so there is no difference between what the doctor pays for a drug and what he is reimbursed, and no Medicaid "spread" to market. *See* N.Y. Soc. Serv. Law s. 367-a(9)(a).

First, the State's theory that brand-name prescription drug manufacturers give steep and undisclosed discounts to pharmacists and then market the Medicaid reimbursement "spreads" to them so that they will "recommend defendants' drugs to Medicaid recipients and their physicians" makes no sense. Doctors, not pharmacists, decide what brand-name prescription drugs are dispensed to Medicaid patients. It makes no economic sense for brand name manufacturers to give steep discounts to pharmacists -- who do ***not*** make prescribing decisions -- and thereby sacrifice substantial revenues.[52] If the State has any factual evidence of this counter-intuitive practice, New York pleading rules require that it plead specific facts relating to specific products sold to specific New York pharmacists.

Second, the State's general contention that the defendants are not disclosing the prices at which they are selling their products in the New York retail pharmacy market is inconsistent with the State's regulatory regime. The State pleads that each defendant participates in the New York EPIC Program. What the State does not say is that, as explained above, that Program requires the defendants to provide quarterly reports, for each EPIC-covered drug, specifying the manufacturers' "Average Manufacturers Price" (AMP) for each EPIC-covered drug and "Best Price" for certain drugs, as those terms are defined under the federal Medicaid Rebate statute.[53] The defendants' AMPs and Best Prices are used to determine both EPIC and New York Medicaid rebates, which substantially reduce the net cost to the State of defendants' drugs. The disclosure by the defendants to the State of this statutorily-defined pricing information provides

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52 The State does not, and cannot, allege that New York physicians are actually making prescribing decisions based on what brand-name drugs are being "recommended" by New York pharmacists.

53 *See* discussion of EPIC Program in Background Section above; *see also*, New York Dep't of Health Website: *Standard Contract For Manufacturers Drug Rebates*, at II(a), II(c) (Defs. App. Ex. M at 5-7).

the State with a simple method of determining the average and "best" prices at which retail pharmacy-dispensed drugs are distributed in New York.

The State's Medicaid anti-kickback claims should be dismissed because the defendants' disclosure of AMP and Best Price information to the State, by itself, defeats the State's claims. The New York anti-kickback statute, on which the regulation cited in the complaints is based, explicitly requires the pleading of facts to show that a defendant acted with "intent to defraud." New York Social Services Law Section 366-f.[54] Here, there could have been no intent to defraud the State with respect to retail pharmacy market pricing (including discounting, if any) because that pricing -- in the form of statutorily defined AMPs and Best Prices -- was disclosed to the State through the EPIC program.[55]

Finally, as with all of its other claims, the State has failed to satisfy its burden to plead its kickback allegations with specificity. The State is brashly seeking to bring kickback claims without identifying a single alleged kickback to a single pharmacist related to a single drug or a single transaction for a single price reimbursed at a single reimbursement rate. The State fails to provide any specifics despite its ability to examine the AMP and "Best Price" pricing data

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[54] In addition, the federal anti-kickback statute (the scope of which circumscribes the New York anti-kickback statute, New York Social Services Law Section 366-f. 1(c), has a scienter requirement like the New York "intent to defraud" requirement. *See Hanlester Network v. Shalala*, 51 F.3d 1390, 1400 (9th Cir. 1995); *see also United States v. Starks*, 157 F.3d 833 (11th Cir. 1998).

[55] The New York regulation cited by the State also exempts, on its face, discounts disclosed to the State and the "client," *i.e.*, the Medicaid recipient. As noted, defendants' reported AMP and Best Price information to the State. There is no practical way for pharmaceutical manufacturers to disclose discounts to Medicaid recipients, given the multiple intervening actors in the distribution chain (*i.e.* wholesalers, prescribing physicians and pharmacists) and patient confidentiality issues. Moreover, to the extent the New York regulation purports to impose such an impossible discount reporting requirement on pharmaceutical manufacturers, it would be an impermissible expansion of the New York statute under which it was promulgated (which has the same discount safe harbor as the federal anti-kickback statute, which in turn does not contain such a client reporting requirement). *See Government Audits Probe Potential Fraud and Abuse by Physicians and Health Facilities*, 74-AUG N.Y. St. B. J. 8 ("Any activity covered by exemptions or safe harbors under the federal anti-kickback laws and regulations are specifically exempted from the [New York] statute's reach."); 42 U.S.C. Section 1320a-7b(b)(3)(A).

provided by the defendants to the State through the EPIC program. Pleading by theory is not enough (especially when the theory makes no economic sense and the State has been provided with pricing data that contradicts its theory), and this claim should be dismissed for its lack of specificity alone.

In sum, the State's anti-kickback claim should be dismissed because (a) it makes no economic sense that defendants would give systematic kickbacks to pharmacists, when it is physicians who determine which of defendants' drugs to prescribe, (b) defendants have, for years, been disclosing to the State specific statutorily defined pricing information concerning retail pharmacy sales, and (c) the state fails to identify a single kickback for a single drug sold to a single pharmacy.

G. The State Has Failed to State a Cause of Action for Repeated and Persistent Obtaining of Public Funds by False Statements

The Fifth Cause of Action of the State's complaints purports to bring a claim for violation of Executive Law § 63(12) for repeatedly "obtaining public funds by false statements," in violation of Social Services Law § 145-b. That statute provides that "[it] shall be unlawful for any person, firm or corporation knowingly, by means of a false statement or representation, or by deliberate concealment of any material fact, or other fraudulent scheme or device, on behalf of himself or others, to attempt to obtain payment from public funds for ... supplies furnished . . . pursuant to" the Medicaid Program or EPIC.

In support of the State's cause of action under Social Services Law § 145-b, the State alleges that "[defendants] have knowingly made false statements and representations or engaged in a fraudulent scheme on behalf of New York pharmacists, resulting in the overpayment of

public funds for [defendants'] prescription drugs covered by New York Medicaid or EPIC," as described "above" in the complaints. Complaints ¶ 50.

As an initial matter, this allegation, like all of the others, suffers from a fatal lack of specificity. Assuming that the "representations" the State is referring to are the statements about prices that the defendants allegedly made to the price reporting services, as noted above, the State has not provided a single specific allegation about a single inflated WAC or AWP or other allegedly reported price about a single named prescription drug, let alone any specific information concerning the alleged falsity or fraudulent nature of any such specific statement. The State cannot proceed on this claim without identifying the statements or representations it claims were false, and why. In addition, for all the reasons set forth above, the State cannot square its "false statements" claim concerning defendants' price reporting with the overwhelming public record concerning the understood meaning of AWPs.

At any rate, by its terms, this claim is limited. It is not asserted on behalf of Medicare beneficiaries, because state funds are not involved in any way in the Medicare program. Nor is this claim made on behalf of Medicaid and EPIC co-payors who, due to their flat co-payments, have no claims in any event. Furthermore, the claim cannot be made with respect to any reimbursements paid to physicians, because EPIC does not cover physician-administered drugs and the New York Medicaid program reimburses physicians for drugs they administer at actual acquisition cost. Accordingly, this cause of action is asserted only on behalf of the State for moneys it paid under Medicaid and EPIC for drugs dispensed by a pharmacist.

The State's False Statements claim on behalf of Medicaid and EPIC for reimbursement payments to retail pharmacies fails to allege facts to support an essential element of the claim:

that the defendant "on behalf of himself, or others . . . attempt[ed] to obtain or . . . obtain[ed] payments from public funds." Social Services Law § 145-b. There is no allegation anywhere in the complaints that the defendants ever received one penny of public funds, either to keep for themselves or to pass through to another party. The fact is that the defendants do not submit claims for, nor do they receive, any public funds.

It is clear from the case law interpreting Social Services Law § 145-b that the statute is aimed at individuals, firms or corporations who ***submit*** false claims for health care services to the state and ***thereby seek to obtain state funds***.[56] There is no allegation in the complaints that defendants submitted a single reimbursement claim to the State in an effort to receive Medicaid or EPIC funds, which also renders this claim fatally defective.

Finally, defendants are aware of no reported decision that has permitted a Social Services Law § 145-b claim to go forward where there is such a tenuous connection between the challenged conduct and the obtaining of public funds as what the State alleges here. As discussed above, the State has generally alleged that defendants submitted "various forms" of price information to third-party price reporting services (not to the government); that the price reporting services, in turn, published a reported AWP; that health care providers bought drugs from defendants at discounts and they (not the defendants) submitted claims for reimbursement;

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56 *See e.g., Zuttah v. Wing*, 243 A.D.2d 765, 674 N.Y.S.2d 130 (3d Dep't 1997) (action against physician for filing false claims for unfurnished medical care); *Garofalo v. Dowling*, 223 A.D.2d 770, 635 N.Y.S.2d 986 (3d Dep't 1996) (finding radiologist guilty of failing to maintain adequate records and submitting claims for inappropriate services); *State v. Easton*, 169 Misc. 2d 282, 647 N.Y.S.2d 904 (Sup. Ct. Albany Cty., 1995) (claim against two corporations to hold them liable for and enforce judgment obtained against their president, who was a physician who fraudulently billed Medicaid for "home visits" that were not actually performed); *People v. Brooklyn Psychosocial Rehabilitation Inst.*, 185 A.D.2d 230, 585 N.Y.S.2d 776 (2d Dep't 1992) (holding corporate officer personally liable for fraudulent Medicaid billings by mental health facilities where defendant designed, supervised and implemented policies which led to fraudulent billings); *State v. Britt*, 141 A.D.2d 911, 529 N.Y.S.2d 228 (3d Dep't 1988) (action against president of word processing company alleging violation of Social Services Law § 145-b for seeking payment from the State for services the company had not rendered).

and that Medicaid and EPIC -- although they had other options -- chose to rely on published AWPs in setting reimbursement rates. Given all of intervening links in the casual chain, the defendants can not possibly be said to have been the ones that "obtained" public funds through false statements. Thus, for this reason alone, the Fifth Cause of Action should be dismissed as well.

Conclusion

For the reasons stated above, GSK, Pharmacia and Aventis respectfully request that the complaints in the above-captioned matters be dismissed.

Respectfully submitted,

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